TITLE OF INVENTION

Needleless Hypodermic Jet Injector Apparatus and Method

BACKGROUND OF THE INVENTION

The present invention relates generally to a multiple-use needle-free (or needle-less) hypodermic jet injection devices, and to methods of reliably delivering the drug through the skin. More particularly, this present invention relates to such a device and to such method which provide an indication that the skin was sufficiently pierced by the jet to ensure that the drug was delivered. The indication is provided through measurement of the impedance.

Needle-less or needle-free hypodermic jet injection devices have been in commercial use for over 30 years. Various needleless hypodermic injection devices have been known and used in the past. These devices, also known as jet injectors, typically use highly accelerated jet of liquid moving sufficiently fast to pierce through the skin and enter the underlying tissues. The advantages of needleless devices are: generally less painful experience for patients, absence of needle-pricks, decreased probability of introducing infection, high throughput when delivering vaccinations.

The related technology includes a number of teachings, including:
U.S. Pat. No. 4,596,556, issued Jun. 24, 1986 to J. Thomas Morrow, et al.;
U.S. Pat. No. 4,913,699; issued Apr. 3, 1990 to James S. Parsons;
U.S. Pat. No. 5,730,723, issued Mar. 24, 1998, to Thomas P. Castellano, et al.;
U.S.Pat. No. 6,585,685, issued July 1, 2003 to John Lawrence Staylor, et al.;
and
U.S. Pat No. 6,689,093, issued Feb. 10, 2004, to Sergio Landau.
WIPO publication WO 97/37705 also discloses a disposable needle-less hypodermic jet injector.

Each of these devices has limitations, deficiencies, or disadvantages, as will be apparent in view of the following detailed description of the present

invention. One of the problems of these devices is that the characteristics of needleless or jet injections typically vary with the pressures exerted by the injection device, and the nozzle diameter. The main problem of these devices is related to the significant variability of patient's size, age, sex, and weight, the nature of the injection site, and the viscosity of the injectant. Especially the patient factors variability is critical as epidermis properties vary widely across the population and are affected by gender, age, race, weight, body fat, skin conditions, and other variables. The unresolved problem of prior art is overcoming this inherent variability and guaranteeing that the outer layer of skin, stratum corneum, was sufficiently pierced and the drug was delivered through that layer. Since there is no confirmation that the skin was sufficiently pierced, very high pressure jets are typically selected, which results in more painful drug delivery and unnecessary deep penetration for person with thinner skin. Still there is no absolute certainty that the drug was delivered, putting patient's treatment at risk.

Thus there is a need in improving the control of needleless drug delivery and ensuring that the stratum corneum was sufficiently pierced during application of needleless drug delivery device.

BRIEF SUMMARY OF THE INVENTION

In view of the above, it is an object of this invention to provide a method to control the piercing of the stratum corneum and delivery of the drug or vaccine through the skin during jet injection of the drug or vaccine. If the injection was not successful, the parameters of the jet can be adjusted, and the drug delivery can be repeated.

Further, it is an object of this invention to provide a needle-free jet injection device which provides for monitoring of the skin piercing during the drug delivery, thus ensuring less painful experience for the patient, as the parameters of the jet can be adjusted so as to operate at the necessary jet

speeds to secure piercing of the skin. This will reduce patients discomfort and provide more control of the drug delivery process to the health professional and thus enable to avoid limitations, deficiencies, or disadvantages of the conventional technology.

In the present invention, the impedance between patient's body and the drug delivery device is measured through the liquid jet during the drug delivery process. The liquid jet completes the electrical circuit formed by impedance monitor, drug delivery device, and the patient's body. When the jet pierces stratum corneum, the impedance in the circuit immediately decreases, thus an indicating the successful drug delivery. The impedance monitor then provides a signal, visible, audible, or electronic, indicating that the process of the drug delivery through skin was successful.

Additional objects and advantages of this invention will appear from a reading of the following detailed description of exemplary preferred embodiment of the invention, taken in conjunction with the appended drawing Figures.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows the preferred embodiment of the invention. A jet drug delivery device 100 with a nozzle 110, said nozzle forms and directs the liquid jet 120 onto a patient's body 130. The outer layer of skin, stratum corneum 140, is penetrated by the liquid jet 120. An impedance monitor 150 is connected to the patient's body through electric wire 180 via connection pad 160, situated on the patient's body. The impedance monitor 150 is also connected through electric wire 170 to the nozzle 110. A signal generator 200, is providing audible, visible, or electronic signal indicating successful or unsuccessful piercing of stratum corneum.

Figure 2 shows the liquid jet 120 penetrating the outer layer of skin, stratum corneum 140. This successful penetration will result in decrease in impedance and thus signal a successful drug delivery.

Figure 3 shows the liquid jet 120 which fails to penetrate the outer layer of skin, stratum corneum 140. This unsuccessful penetration will not result in decreased impedance and thus signal a non-successful drug delivery.

DETAILED DESCRIPTION OF THE INVENTION

Referring to Figure 1, the electric circuit is formed between impedance monitor 150, patient's body, and liquid jet drug delivery device. Prior to the activation of liquid jet, the circuit is open and the impedance is very high, corresponding to open circuit impedance. The closing of the circuit is achieved by activating the liquid jet. Once the jet touched the patient's body, the circuit is closed and electric current can pass from the impedance monitor 150 into the drug delivery device nozzle 110 via wire 170 , then into the liquid jet 120, then into patient's body 130, then into the connection pad 160, then back into the impedance monitor via wire 180. Thus during the liquid jet drug delivery, the electric circuit is established and enabled to measure impedance.

Once the liquid jet touched the patient's body, the impedance is principally determined by patient's skin, particularly stratum corneum, which has highest electric resistance in the circuit.

If the jet fails to penetrate the stratum corneum, the impedance monitor will measure relatively high impedance and will provide feedback indicating that the grug deliver was unsuccessful.

By dynamically monitoring the impedance through the liquid jet, the depth of the penetration of the liquid jet can be estimated based on the different impedance properties of the tissue as one penetrates deeper into the body.

The impedance monitoring or measuring devices are well known in the art. Such devices can be further connected to a computer for dynamic analysis of the impedance during the jet injection and for providing corresponding signal, which is preferably audible or optical signal, or signal in the form of computer output.

Many possible variations of the method and apparatus within the defined parameters of the present invention are apparent to those skilled in the art, without further explanation, and those variants are intended to be included within the broad scope of the invention.